

REMARKS

In the Final Action dated January 13, 2005, claims 47-59 are pending. Claims 49 and 50 are withdrawn from further consideration as drawn to non-elected subject matter. Claims 47, 48 and 51-59 are under examination. Claims 58-59 are objected to for certain informalities. Claims 51-55 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Claim 59 is rejected under 35 U.S.C. § 112, first paragraph, for allegedly reciting subject matter not disclosed in the specification as originally filed. Claims 47-48 and 51-59 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to satisfy the written description requirement. Claims 47-48, and 51-59 are further rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking enabling support in the specification.

In a telephone interview conducted on March 15, 2005, the Examiner indicated that claim 58 would be allowable if rewritten as an independent claim. The Examiner also requested submission of argument and/or evidence in support of the subject matter of claims 48 and 59.

Applicant, through the undersigned, wishes to thank Examiner McElwain for the courtesy and assistance extended on behalf of the Applicant during the telephone interview.

In response to the Final Action and consistent with the Examiner's suggestion during the interview, Applicant submits the instant amendment to the claims, which in view of the following remarks, is deemed to place the present application in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

Claims 58-59 are objected to for reciting "an isolated", instead of "The isolated". It is submitted that claims 58 and 59 have been rewritten as independent claims. Thus, the objection to claims 58-59 is overcome. Withdrawal of the objection to the claims is therefore respectfully requested.

Claims 51-55 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. However, the Examiner has not stated the reasons for raising the rejection. It is respectfully submitted that claims 51-55, as presently recited, are not indefinite.

Claim 59 is rejected under 35 U.S.C. § 112, first paragraph, for allegedly reciting subject matter not disclosed in the specification as originally filed. Specifically, the Examiner alleges that the recited peptide fragments are not disclosed in the specification.

Applicant respectfully submits that the fragments recited in claim 59 are disclosed in the specification, e.g., in Table 3, first row, on page 40. Claim 59 has been amended to include the sequence identifiers that represent the peptide fragments, as the Examiner suggested during the telephone interview. Support for the amendment to claim 59 is also found in Table 3, first row, on page 40 of the specification. The rejection of claim 59 under 35 U.S.C. § 112, first paragraph, is therefore overcome. Withdrawal of the rejection is respectfully requested.

Claims 47-48 and 51-59 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to satisfy the written description requirement.

Specifically, the Examiner maintains that the specific structural features that are required for delta-6 desaturase activity and that define the claimed genus, are not described in the specification. In this connection, the Examiner refers to Table 3 of the present application, in which the histine motifs from a number of desaturases of various plant species are compared. The Examiner contends that the differences between the motifs from various species are significant.

During the telephone interview, the Examiner indicated that claim 58 would be allowable if rewritten as an independent claim.

Applicant has rewritten claim 58 as an independent claim. Applicant has also canceled claim 47, and has rewritten claims 48 and 59 as independent claims. Applicant therefore addresses the rejection in respect to claims 48 and 59 as follows.

Claim 48, as presently amended, is directed to an isolated nucleic acid that codes for a plant delta-6 desaturase wherein the plant delta-6 desaturase is characterized by having at least one of SEQ ID NO: 6, 12 or 20. As disclosed in the specification, SEQ ID NOS: 6, 12 and 20 represent the three histidine motifs in the Borage delta-6 desaturase. Claim 59, as presently recited, is directed to an isolated nucleic acid that codes for a plant delta-6 desaturase and that hybridizes to a nucleotide sequence coding for a plant delta-6 desaturase which comprises one or more of the three histidine motifs of the Borage delta-6 desaturase.

Applicant respectfully submits that the nucleic acids of claims 48 and 59, as presently claimed, are adequately described in the specification. Applicant respectfully submits that the specification describes, by way of examples, the *Borage* and *Evening Primrose* delta-6 desaturase DNAs. The specification also describes assays, which were routine to those skilled in the art, for determining the enzymatic activity of a plant delta-6 desaturase DNA, i.e., the conversion of linolenic acid (LA) to gamma linolenic acid (GLA). See, for example, page 7, lines 23-28, page 10, lines 25-29, and page 11, lines 1-4, 25-28 of the specification. Furthermore, the specification describes structural characteristics of a delta-6 desaturase encoded by the claimed nucleic acid. In particular, the specification teaches structural motifs in the *Borage* delta-6 desaturase, namely, the Lipid Box, the Metal Box 1, and the Metal Box 2. See page 39, lines 12, 13, and Table 3 of the specification. The specification further describes, the three nearly identical motifs, renamed as "histidine-rich" motifs, in the *Evening Primrose* delta-6 desaturase. See page 48, lines 26-28, and page 49, lines 2-12. The specification also teaches, at

page 48, lines 26, 27, that the three histidine-rich motifs are common structural features present in all plant delta-6 desaturases. In addition, the specification discloses, in page 11, lines 27, 28 and page 12, lines 1-11, that DNA sequences encoding plant delta-6 desaturases can be isolated by hybridization based on the *Borage* or *Evening Primrose* delta-6 desaturase DNA.

Applicant respectfully submits the histine motifs are well conserved among plant delta-6 desaturases, as shown in the present specification and in the literature publications provided in Applicant's previous response. With respect to the Examiner's assertion regarding Table 3, Applicant submits that not all the desaturases in Table 3 are delta-6 desaturases. In order to clearly demonstrate the conservation of the histidine motifs, Applicant provides **Exhibit 1** which tabulates the motifs of various plant delta-6 desaturases.

Applicant respectfully submits that enzymatic assay (function) and the three conserved histine motifs (structure), preferably in combination with hybridization characteristics, adequately describe the genus of plant delta-6 desaturases. Applicant's position is also consistent with the decision in *Enzo Biochem v. Gen-probe, Inc.*, 323 F.3d 956, at 964 (Fed. Cir. 2002). The Court in *Enzo Biochem* addressed the factors in determining whether the written description requirement is met.

"It is not correct, however, that all functional descriptions of genetic material fail to meet the written description requirement. . . the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . *i.e.*, complete or partial structure, other physical and/or chemical properties, *functional characteristics when coupled with a known or disclosed correlation between function and structure*, or some combination of such characteristics.'"

See *Enzo Biochem* at 964 (emphasis in original).

The court in *Enzo Biochem* also stated that the written description requirement is met if one skilled in the art finds the generically claimed sequences, described on the basis of the disclosure of the hybridization function and an accessible structure, consistent with the United States Patent and Trademark Office (USPTO) Guidelines. According to the USPTO Guidelines, claims by functional language are permissible when the claimed material hybridizes to a disclosed substrate. See *Enzo Biochem* at 968.

Applicant respectfully submits that the specification discloses sufficiently detailed and relevant identifying features of the claimed molecules, e.g., the function of the encoded protein as a plant delta-6 desaturase (determined by an enzymatic assay as disclosed), the three histidine- rich motifs, and the hybridization features. Those skilled in the art would understand that Applicant had possession of a DNA encoding a plant delta-6 desaturase at the time the application was filed. Thus, Applicant respectfully submits that the present application fully complies with the written description requirement under 35 U.S.C. § 112, first paragraph.

In view of the foregoing, Applicant respectfully requests that the Examiner withdraw the rejection based on the written description requirement of 35 U.S.C. § 112, first paragraph.

Claims 47-48 and 51-59 are further rejected under 35 U.S.C. § 112, first paragraph, allegedly because the specification does not provide enablement for delta-6 desaturases from all plant species.

Specifically, the Examiner maintains that it would take undue experimentation for those skilled in the art to make and use the claimed nucleic acids, as set forth in the previous Office Action. Previously, the Examiner alleged that the specification does not teach what sequences the claimed nucleic acid molecules have in common that identify the molecules as delta-6 desaturase genes.

As submitted above, Applicant has rewritten claim 58 as an independent claim which is considered to be allowable. Applicant has also canceled claim 47, and has rewritten claims 48 and 59 as independent claims. Applicant respectfully submits that the subject matter of claims 48 and 59 and their dependent claims, as presently claimed, are fully enabled by the specification.

Applicant respectfully submits that the claims presently recite "plant delta-6 desaturase" and specific structural characteristics of plant delta-6 desaturases, e.g., the histidine-rich motifs. Claim 59 also recites certain hybridization characteristics. Based on the teaching in the specification, those skilled in the art would be able to identify a plant delta delta-6 desaturase gene, as presently claimed, without undue experimentation. In this regard, Applicant respectfully submits that both the assay for determining the enzymatic activity of delta-6 desaturases, and hybridization techniques, are fairly routine to those skilled in the art. The structural features, i.e., the histidine-rich motifs, certainly also facilitate the identification of a gene as coding for a delta-6 desaturase.

As evidence that identification of additional plant delta-6 desaturases genes would not be undue, Applicant respectfully directs the Examiner's attention to the publications submitted in the previous response: Sperling et al., *Eur. J. Biochem.*, 267:3801-3811 (2000), Girke et al., *The Plant Journal*, 15:39-48 (1998) and Garcia-Maroto, *Lipids*, 37:417-426 (2002).

In Sperling et al., the delta-6 desaturase from the plant, *Ceratodon purpureus*, was identified and characterized using primers derived from the sequences encoding or surrounding histidine-rich domains and a yeast gain of function assay.

In Girke et al., the delta-6 desaturase cDNA of *Physcomitrella patens* was identified using primers derived from sequences encoding or surrounding similar histidine-rich motifs, and a function assay that included the profiling of fatty acids by gas liquid chromatography.

In Garcia-Maroto, the genes encoding the delta-6 desaturase of two plants, *Echium gentianoides* and *Echium pitardii*, were identified and characterized using primers derived from sequences encoding or surrounding similar histidine-rich motifs.

In view of the foregoing, Applicant respectfully submits that those skilled in the art would be able to isolate a plant delta-6 desaturase gene, as presently claimed, without undue experimentation. Withdrawal of the rejection based on the enablement requirement, is therefore respectfully requested.

In view of foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



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Encls.: Exhibits 1-7

EXHIBIT 1

Histidine-Rich Motifs Of Plant Delta-6 Desaturases

Plant	Motif 1	Motif 2	Motif 3	Source
Borage	WLGHDAGH	FNVAHH	FQLEHH	This application, page 40, Table 3, row 1.
Evening Primrose	YVGHDSGH	FNVAHH	FQLEHH	This application, SEQ ID NO: 27 and Figure 11.
Echium gentianoides	WLGHDAGH	FNVAHH	FQVEHH	Genbank Accession No. AAL23580 (attached Exhibit 2); Garcia-Maroto (Lipids 2002, enclosed in Response dated October 14, 2004).
Echium pitardii var. pitardii	WLGHDAGH	FNVAHH	FQVEHH	Genbank Accession No. AAL23581 (attached Exhibit 3); Garcia-Maroto (Lipids 2002, enclosed in Response dated October 14, 2004).
Camellia sinensis	WAGHDSGH	FNVAHH	FQLEHH	Genbank Accession No. AAO13090 (attached Exhibit 4)
Argania spinosa	WLGHDPSGH	FNVAHH	FQLEHH	Genbank Accession No. AAM94345 (attached Exhibit 5)
Oryza sativa	WMGHDSGH	FNVAHH	FQLEHH	Genbank Accession No. BAD28708 (attached Exhibit 6)
Primula vialii	WLGHDPSGH	FNVAHH	FQVEHH	Genbank Accession No. CA158893 (attached Exhibit 7)

LOCUS AAL23580 448 aa linear PLN 01-DEC-2001

DEFINITION delta-6-desaturase [Echium gentianoides].

ACCESSION AAL23580

VERSION AAL23580.1 GI:17223795

DBSOURCE accession AY055117.1

KEYWORDS

SOURCE Echium gentianoides

ORGANISM Echium gentianoides

Eukaryota; Viridiplantae; Streptophyta; Embryophyta;

Tracheophyta;

Spermatophyta; Magnoliophyta; eudicotyledons; core eudicots; asterids; lamiids; Boraginaceae; Echium.

REFERENCE 1 (residues 1 to 448)

AUTHORS Maroto, F.G., Alonso, D.L., Garrido, J.-A.S., Ferron, M.V. and Ruiz, J.R.

TITLE Cloning and Molecular Characterization of the D6-Desaturase from

Echium: Functional Expression in Yeast and Tobacco

JOURNAL Unpublished

REFERENCE 2 (residues 1 to 448)

AUTHORS Maroto, F.G., Alonso, D.L., Garrido, J.-A.S., Ferron, M.V. and Ruiz, J.R.

TITLE Direct Submission

JOURNAL Submitted (10-SEP-2001) Biochemistry, Universidad de Almeria, Campus Universitario, La Canada s.n., Almeria 04120, Spain

FEATURES Location/Qualifiers

source

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/organism="Echium gentianoides"

/db_xref="taxon:173991"

/note="authority: Echium gentianoides Webb ex Coincy. Bull. Herb. Boiss., ser. 2, 4: 498 (1903)"

Protein

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/name="acyl-lipid desaturase"

CDS

1..448

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/coded_by="AY055117.1:37..1383"

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121 ammfamsvyg vlfceglvh llagglmgfv wiqsgwigho aghyivmpnp rlnklmgiva
181 gnclsgisig wwkwnmanh iacnslidydp dlqyipflvv ssklfsslts hfyekkltdf
241 slsrffvshq hwtfypvmcs arvnmfvqsl imlltkrnvf yrsqellglv vfwiiwypllv
301 sclpnwgeri mfvvaslsvt gmqqvqfsln hfsasvyvgq pkgndwfekq tcgtldiscp
361 swmdwfhggl qevvnlfp klprchlрки spfvmelckk hnlsyncasf seanemtirt
421 lrdtalqard ltkplpknlv wealnthg

//

LOCUS AAO13090 448 aa linear PLN 01-NOV-2004

DEFINITION delta-6-desaturase [Camellia sinensis].

ACCESSION AAO13090

VERSION AAO13090.1 GI:37727301

DBSOURCE accession AY169402.1

KEYWORDS

SOURCE Camellia sinensis (black tea)

ORGANISM Camellia sinensis

Eukaryota; Viridiplantae; Streptophyta; Embryophyta;

Tracheophyta;

Spermatophyta; Magnoliophyta; eudicotyledons; core eudicots; asterids; Ericales; Theaceae; Camellia.

REFERENCE 1 (residues 1 to 448)

AUTHORS Park, J.-S., Kim, J.-B., Kim, K.-H. and Kim, Y.-H.

TITLE Direct Submission

JOURNAL Submitted (27-OCT-2002) Metabolic Engineering Division, National

Institute of Agricultural Biotechnology, 225, Seodun-Dong,

Suwon,

Kyunggodo 441-707, Republic of Korea

COMMENT Method: conceptual translation supplied by author.

FEATURES Location/Qualifiers

source

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Protein

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CDS

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121 allfsvsvwg vlccssiwhv lvcgglmzgl wiqsgwaghe schyqimpsk klnrfvqilt
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241 svtrlfvsyq hwtfypvmcf arlnlfapsf mlleskrkvp nrveeilgis vfwyldpllv
301 sclpnlgerl mfvlasfavs giqhvqfcln hfssivvygp psgtdwcgkq trgtlditcp
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421 lrnaalqard vanpvqknlv weavnthg
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LOCUS AAM94345 448 aa linear PLN 17-AUG-2002

DEFINITION delta-6-desaturase-[Argania spinosa].

ACCESSION AAM94345

VERSION AAM94345.1 GI:22296826

DBSOURCE accession AY131238.1

KEYWORDS

SOURCE Argania spinosa

ORGANISM Argania spinosa

Eukaryota; Viridiplantae; Streptophyta; Embryophyta;

Tracheophyta;

Spermatophyta; Magnoliophyta; eudicotyledons; core eudicots; asterids; Ericales; Sapotaceae; Argania.

REFERENCE 1 (residues 1 to 448)

AUTHORS El Filali,A., Anderson,M. and Abbas,K.

TITLE Characterization and cloning of delta-6-desaturase in Argania spinosa fruit

JOURNAL Unpublished

REFERENCE 2 (residues 1 to 448)

AUTHORS El Filali,A., Anderson,M. and Abbas,K.

TITLE Direct Submission

JOURNAL Submitted (12-JUL-2002) Biologie Moleculaire, Faculte des Sciences,

Ibn Batouta, Rabat, Rabat 1014, Morocco

COMMENT Method: conceptual translation supplied by author.

FEATURES Location/Qualifiers

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Protein 1..448

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CDS 1..448

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241 slsrffvsyq hwtfytimca arlnmyvqsl imlltkrnvs yrahellgcl vfsiwypll
301 sclpnwgeri mfviaslsvt gmqqvqfsln hfsssvyvgk pngnnwfetq tdgtldiscp
361 pwwdwfhggl qfqlenlfp kmprcnlrti spyvielckk hnlpynyasf skanemtlrt
421 lrntalqard itkplpknlv wealhtg
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LOCUS AAL23581 448 aa linear PLN 01-DEC-2001

DEFINITION delta-6-desaturase [Echium pitardii var. pitardii].

ACCESSION AAL23581

VERSION AAL23581.1 GI:17223797

DBSOURCE accession AY055118.1

KEYWORDS .

SOURCE Echium pitardii var. pitardii

ORGANISM Echium pitardii var. pitardii

Eukaryota; Viridiplantae; Streptophyta; Embryophyta;

Tracheophyta;

Spermatophyta; Magnoliophyta; eudicotyledons; core eudicots; asterids; lamiids; Boraginaceae; Echium.

REFERENCE 1 (residues 1 to 448)

AUTHORS Maroto, F.G., Alonso, D.L., Garrido, J.-A.S., Ferron, M.V. and Ruiz, J.R.

TITLE Cloning and Molecular Characterization of the D6-Desaturase from

Echium: Functional Expression in Yeast and Tobacco

JOURNAL Unpublished

REFERENCE 2 (residues 1 to 448)

AUTHORS Maroto, F.G., Alonso, D.L., Garrido, J.-A.S., Ferron, M.V. and Ruiz, J.R.

TITLE Direct Submission

JOURNAL Submitted (10-SEP-2001) Biochemistry, Universidad de Almeria, Campus Universitario, La Canada s.n., Almeria 04120, Spain

FEATURES Location/Qualifiers

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/note="authority: Echium pitardii A. Chev., Fl. Cap.

Vert:

183 (1935)"

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/name="acyl-lipid desaturase"

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LOCUS BAD28708 466 aa linear PLN 13-JUL-2004
 DEFINITION putative delta-6-desaturase [Oryza sativa (japonica cultivar-group)].
 ACCESSION BAD28708
 VERSION BAD28708.1 GI:50252533
 DBSOURCE accession AP005554.3
 KEYWORDS .
 SOURCE Oryza sativa (japonica cultivar-group)
 ORGANISM Oryza sativa (japonica cultivar-group)
 Eukaryota; Viridiplantae; Streptophyta; Embryophyta; Tracheophyta;
 Spermatophyta; Magnoliophyta; Liliopsida; Poales; Poaceae; Ehrhartoideae; Oryzeae; Oryza.
 REFERENCE 1
 AUTHORS Sasaki, T., Matsumoto, T., Hattori, M., Sakaki, Y. and Katayose, Y.
 TITLE Oryza sativa nipponbare (GA3) genomic DNA, chromosome 9, BAC clone: OJ1118_A10
 JOURNAL Published Only in Database (2002)
 REFERENCE 2 (residues 1 to 466)
 AUTHORS Sasaki, T., Matsumoto, T., Hattori, M., Sakaki, Y. and Katayose, Y.
 TITLE Direct Submission
 JOURNAL Submitted (23-JUL-2002) Takuji Sasaki, National Institute of Agrobiological Sciences, Rice Genome Research Program; Kannondai
 2-1-2, Tsukuba, Ibaraki 305-8602, Japan
 (E-mail: tsasaki@nias.affrc.go.jp,
 URL: <http://rgp.dna.affrc.go.jp/>,
 Tel: 81-298-38-7441, Fax: 81-298-38-7468)
 COMMENT Genes were predicted from the integrated results of the following:
 GENSCAN (<http://CCR-081.mit.edu/GENSCAN.html>), FGENESH (<http://www.softberry.com/>), GeneMark.hmm (<http://opal.biology.gatech.edu/GeneMark/>), GlimmerM (http://www.tigr.org/tdb/glimmer/glmr_form.html), RiceHMM (<http://rgp.dna.affrc.go.jp/RiceHMM/>), SplicePredictor (<http://bioinformatics.iastate.edu/cgi-bin/sp.cgi>), sim4 (<http://globin.cse.psu.edu/html/docs/sim4.html>), gap2 (<http://www.tigr.org/software/glimmer/>), BLASTN and BLASTX.
 The genomic sequence was searched against NCBI NonRedundant Protein database, nr (<ftp://ncbi.nlm.nih.gov/blast/db>) and the cDNA sequence database at RGP or DDBJ. Protein homologies of the coding regions were searched against NCBI NonRedundant Protein database with BLASTP. ESTs represent the identified cDNA sequences using BLASTN with the corresponding DDBJ accession no. and RGP clone ID.
 Full-length cDNAs represent the identified cDNA sequences using BLASTN with the corresponding DDBJ accession no. A gene with identity or significant homology to a protein is classified based on the protein name to indicate the homology level such as same name, 'putative-' and '-like protein'. A gene without significant homology to any protein but with full-length cDNA or EST homology (covering almost the entire length of partial sequence) is classified as an 'unknown' protein. A gene predicted

by two or more gene prediction programs is classified as a
'hypothetical' protein according to IRGSP standard. A gene
predicted by a single gene prediction program is also
classified as

a probable 'hypothetical' protein and is included as a
miscellaneous feature of the sequence.

The orientation of the sequence is from -21M13 to M13rev of the
BAC

clone. This sequence of OJ1118_A10 clone has an overlap with
OJ1253_E02 (DDBJ: AP005566) clone at 5' end and with an overlap
with OJ1104_G11 (DDBJ: AP005091) clone at 3' end. The sequence

was generated by combining Monsanto and RGP-Japan sequencing data.
Detailed information on overlap and assembly quality together

with annotation of this entry is available at
<http://rgp.dna.affrc.go.jp/GenomeSeq.html>.

FEATURES
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 Location/Qualifiers
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 CDS
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 /note="contains EST(s): AU172864 (E31729)
 contains full-length cDNA(s): AK058543"

ORIGIN

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181 hritghaal drllqvlsgn cltglsiaww kcnrtia cnsldhdpdl qhmplfavss
241 klfglwisyfy qrtlvfdaas kflisyqhw fypvmcfari nlliqsavfl lssrkvpqrg
301 leiagvaafw vwypmvvscl pnwwervafv vasfvitgiq hvqfclnhfs sevyvgppkg
361 ndwfekqtag tldiqcspwm dwfhgglqg hchlfprlp rchlrkvspf vrdlckkhgl
421 pyaaasfwqa nvltwktlra aalqarkats gaapknlvwe avnthg
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